

510(k) when using the draft STED format as described in the final guidance document.

(Comment 12) One comment inquires about incentives for manufacturers to participate in the pilot program. Related comments ask that FDA reconsider the devices eligible for the pilot program.

FDA is committed to ensuring that the FDA review process will not be unduly hindered if persons choose to follow the draft STED format. However, FDA cannot assure shorter review timeframes if the draft STED format is used. FDA believes that medical device companies with vision, leadership, a desire to influence the accelerating global harmonization effort, and the goal of ultimately reducing their regulatory burden, will participate in the pilot program. FDA has increased the list of eligible devices to provide more flexibility and believes the pilot program will help achieve an international uniformity of submissions.

(Comment 13) One comment asks that the pilot program focus only on 510(k)s, PMAs, and PMA supplements that are for high risk devices.

FDA has exempted from premarket evaluation virtually all the low risk devices that were subject to premarket requirements. Therefore, the candidates for the pilot program are of a moderate to high degree of risk. PMA supplements are not candidates for the pilot program.

(Comment 14) One comment asks that the same measures of success or failure of the pilot program be identified for all countries conducting the pilot and that FDA clearly define the criteria and analysis methods that will be used.

FDA agrees that measures of success and analytical methods should be clearly defined prior to initiation of the pilot. It is important to determine whether the core of a premarket submission can be based on the draft STED format. Both FDA and SG1 will track and assess whether: (1) There are significant impediments to filing and review of documents, (2) the STED harmonized format has utility for evaluating different regulatory classes of devices having different complexities, and (3) use of the STED harmonized format results in improved regulatory review times. FDA will post a report summarizing the results of its analysis of the pilot on its Web site.

(Comment 15) One comment notes that statutory and/or regulatory changes may be needed to fully implement the draft STED document concept of harmonized premarket submissions in the member countries.

Each of the five GHTF member countries has determined that the pilot

program can proceed without the need for statutory or regulatory changes if current country-specific requirements are met. It remains to be determined how a STED document would be implemented if it becomes an alternative means of submission.

(Comment 16) One comment asks that FDA remove endosseous dental implants from the list of candidate devices for the pilot program. The comment notes that applying the harmonized process to these implants will not provide the agency with the necessary information on their safety and effectiveness.

FDA does not concur with the comment. The FDA draft guidance for the pilot premarket review program and the draft STED document both describe the need for applicants to consider country-specific information, including guidance documents, when preparing their premarket submissions for review. A premarket submission for an endosseous dental implant based on the draft STED format should consider all relevant available guidance documents.

III. Significance of Guidance

This guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a way to apply GHTF recommendations as related to premarket submission to FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

IV. Electronic Access

You may obtain a copy of "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff," via fax machine by calling the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH home page is updated on a regular basis and includes: Civil money penalty guidance documents, device safety alerts, **Federal**

Register reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), assistance for small manufacturers, information on video conferencing, electronic submissions, mammography devices, and other device-related information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0161]

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is adding nonelectric biopsy forceps (classified in 21 CFR 876.1075, *Gastroenterology-urology biopsy instrument*) to the list of critical reprocessed single-use devices (SUDs) whose exemption from premarket notification requirements is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), is necessary in a premarket notification (510(k)). FDA is requiring submission of these data to ensure that reprocessed single-use nonelectric biopsy forceps are substantially equivalent to predicate devices, in accordance with MDUFMA.

DATES: These actions are effective June 26, 2003. Manufacturers of reprocessed